PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/821,229
Filing Date:	April 8, 2004
Applicant(s):	Tara Ziolo et al.
Group Art Unit:	3733
Examiner:	Steven J. Cotroneo
Title:	BONE FIXATION DEVICE
Attorney Docket:	5490E-000365

Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.131

Sir:

I hereby declare under penalty of perjury as follows:

1. That I am one of the inventors of the above-identified application.

2. That the invention was conceived and reduced to practice in this country prior to September 3, 2003—the filing date of United States Publication No. 2005/0049593 to Duong.

3. That the redacted engineering drawings of Exhibit A illustrate the various components of the subject invention that were produced by an in-house manufacturing facility of the assignee and shown to work for their intended purpose prior to September 3, 2003—the filing date of United States Publication No. 2005/0049593 to Duong.

4. The components described above in Section 3 and shown in Exhibit A were tested and shown to function such that cooperation between a first cam of a fastener shaft and a second cam of an annular member resulted in expansion of the annular member in a radial direction from an unexpanded position to an expanded position when the fastener shaft was rotated relative to the annular member. Prior to such rotation, the fastener shaft and annular member were able to freely rotate about an axis of the fastener shaft and collectively seat in a fixation hole of a bone fixation plate at various angles relative to the fixation plate. When the fastener shaft was rotated relative to the annular member to cause the annular member to expand in a radial direction, such expansion prevented the fastener shaft and annular member from backing out of the fixation hole.

5. That each of the redacted drawings of Exhibit A bears a date prior to September 3, 2003.

6. That the invention has never been abandoned, suppressed, or concealed.

7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are being made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, and patent issuing thereon, or any patent to which this verified statement is directed.

Dated: 5/27/10

Rui Ferreira

Dated: 5/19/10

Tara Ziolo

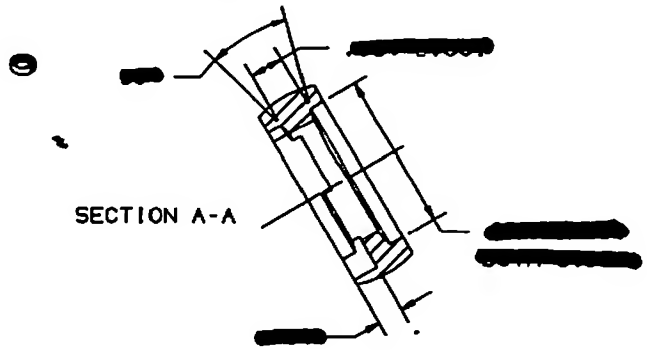
15379297.1

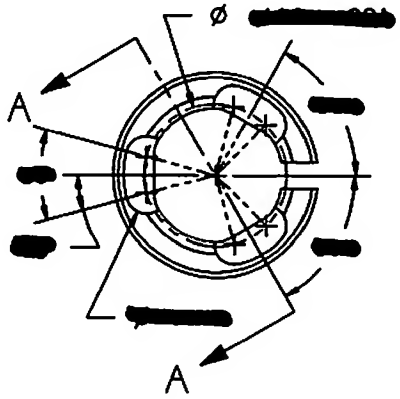
EXHIBIT A

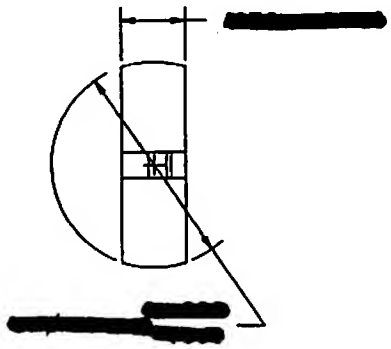
3

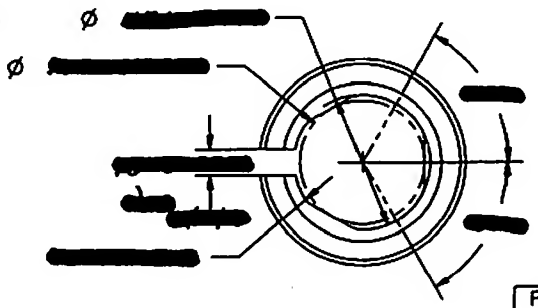
APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM

REVISIONS						
REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRFT	DATE	APPROVED
A			INITIAL PROTOTYPE RELEASE	JTC		









MANUFACTURING

PART NO.
RD-3753

QTY 10

NOTES:

1. ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF 32 OR SMOOTHER UNLESS OTHERWISE SPECIFIED
2. BEAD BLAST PER SPEC #741019
3. PASSIVATE PER SPEC #741000

NEXT ASSY

QTY	PART NUMBER	NOMENCLATURE OR DESCRIPTION	REMARKS	ITEM

LIST OF MATERIALS

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN INCHES
TOLERANCES:
2 PLACE DECIMALS ± .01
3 PLACE DECIMALS ± .005
FRACTIONS ± 1/64
ANGLES ± 1°

MATERIAL T16AI4V

FINISH 1 2 3

HARDNESS

DRAFTER [redacted]
APPROVED
RESPONSIBLE ENG.
QUALITY/RELIABILITY
MANUFACTURING ENG.

[redacted]

TITLE
TRI-CAM PROTOTYPE BUSHING

FIRST USED ON
USED ON PROJ NO

SIZE B | DWG NO. RD-3753 | REV. A

[redacted] SHEET 1 OF 1

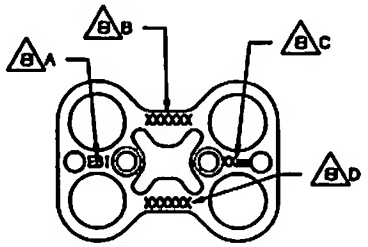
2017

APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM

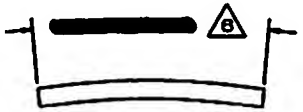
REVISIONS						
REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRFT	DATE	APPROVED
A		DCR-	RELEASED FOR DEVELOPMENT	TZ		

PART NO.	SIZE	DIM A	DIM B	DIM C
[redacted]				

-6 Pc

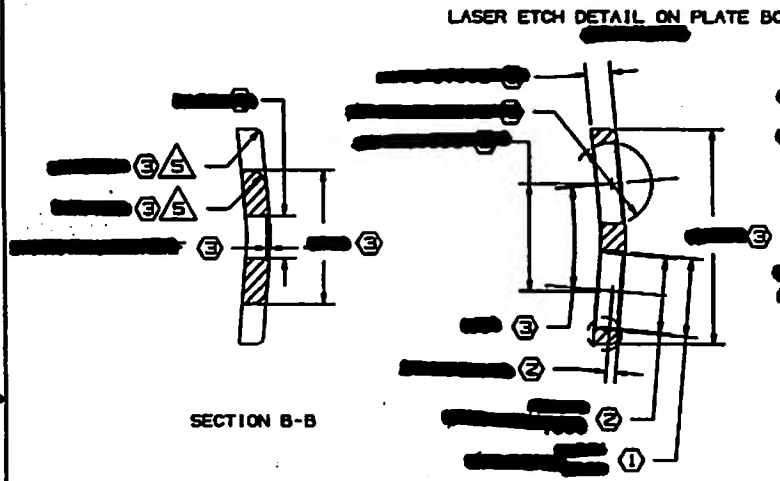


LASER ETCH DETAIL ON PLATE BOTTOM



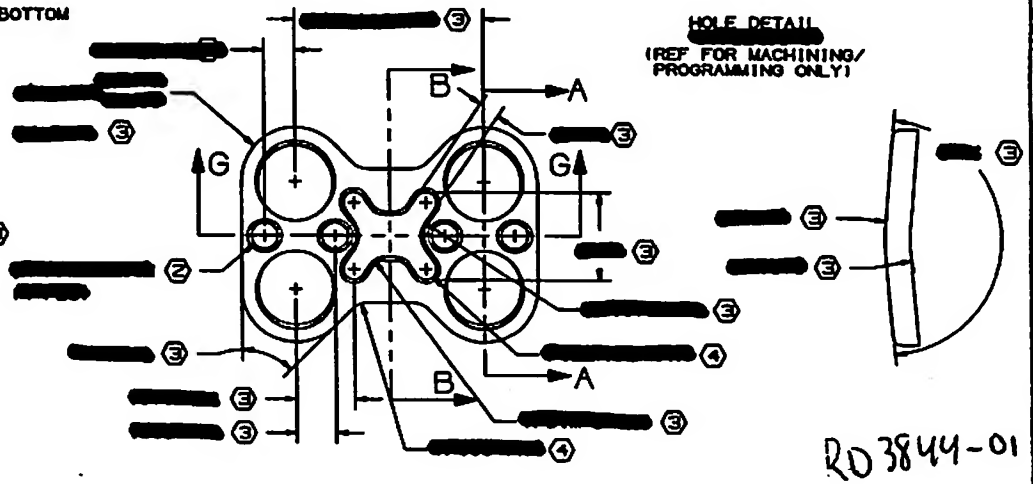
BENDING/FINISHING DETAIL

HOLE DETAIL [redacted]
(REF FOR MACHINING/ PROGRAMMING ONLY)



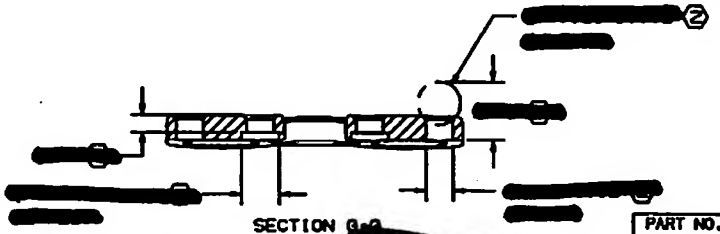
SECTION B-B

SECTION A-A



RD3844-01
Qty 6

RD3844-01
Qty 2

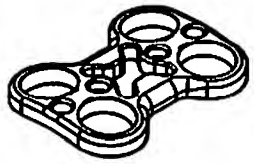


SECTION B-B [redacted]

PART NO. SEE TABLE

NOTES:

1. ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF 32 √ OR SMOOTHER UNLESS OTHERWISE SPECIFIED
2. BEAD BLAST PER SPEC #741019
3. PASSIVATE PER SPEC #741000
4. SYMBOL ○ INDICATES INSPECTION LEVEL. REF PROCEDURE 743001
5. R.050 ON STRAIGHT SIDES PULL RADIUS TOOL OUT ALONG [redacted] TO A PARTIAL RADIUS OF [redacted] ALONG [redacted] ON THE ENDS OF THE PLATE
6. LONGITUDINAL BEND OF [redacted] AFTER MACHINING
7. SEE #741033 FOR HANDLING PRECAUTION
8. LASER ETCH PER SPEC #741005, IN AREAS SHOWN: CHARACTERS ARE TO BE [redacted] REF HIGH
   - A) EBI
   - B) PART NUMBER
   - C) SIZE FROM TABLE
   - D) LOT NO., PER SPEC #741006



ISOMETRIC VIEW [redacted]

MANUFACTURING

QTY	PART NUMBER	NOMENCLATURE OR DESCRIPTION	REMARKS	ITEM

LIST OF MATERIALS

UNLESS OTHERWISE SPECIFIED	DRAWN	
DIMENSIONS ARE IN INCHES	T. ZIOLO	
TOLERANCES:	APPROVED	
2 PLACE DECIMALS ± .01	RESPONSIBLE ENG.	
3 PLACE DECIMALS ± .005	QUALITY/RELIABILITY	
FRACTIONS ± 1/64	MANUFACTURING ENG.	
ANGLES ± 1°		
MATERIAL [redacted]		
FINISH 1 2 3		
HARDNESS		

TITLE: 1-LEVEL PLATE 12MM - 36MM LENGTH

FIRST USED ON	SIZE	DWG NO.	REV.
[redacted]	C	[redacted]	A
		SHEET 1 OF 1	

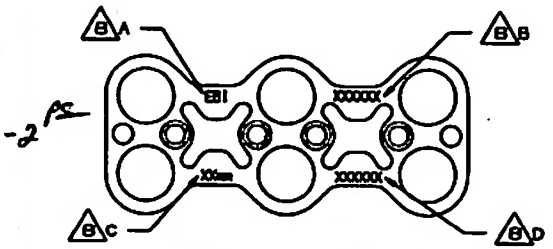
NEXT ASSY

PART NO.	SIZE	DIM A	DIM B	DIM C
[redacted]				

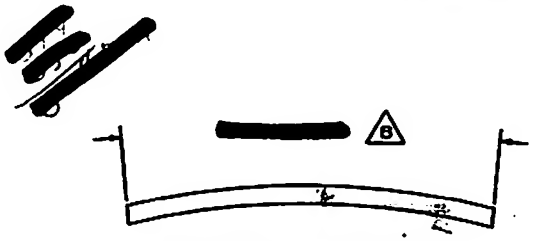
APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM

REVISIONS

REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRFT	DATE	APPROVED
A		DCR-	RELEASED FOR DEVELOPMENT	TZ		

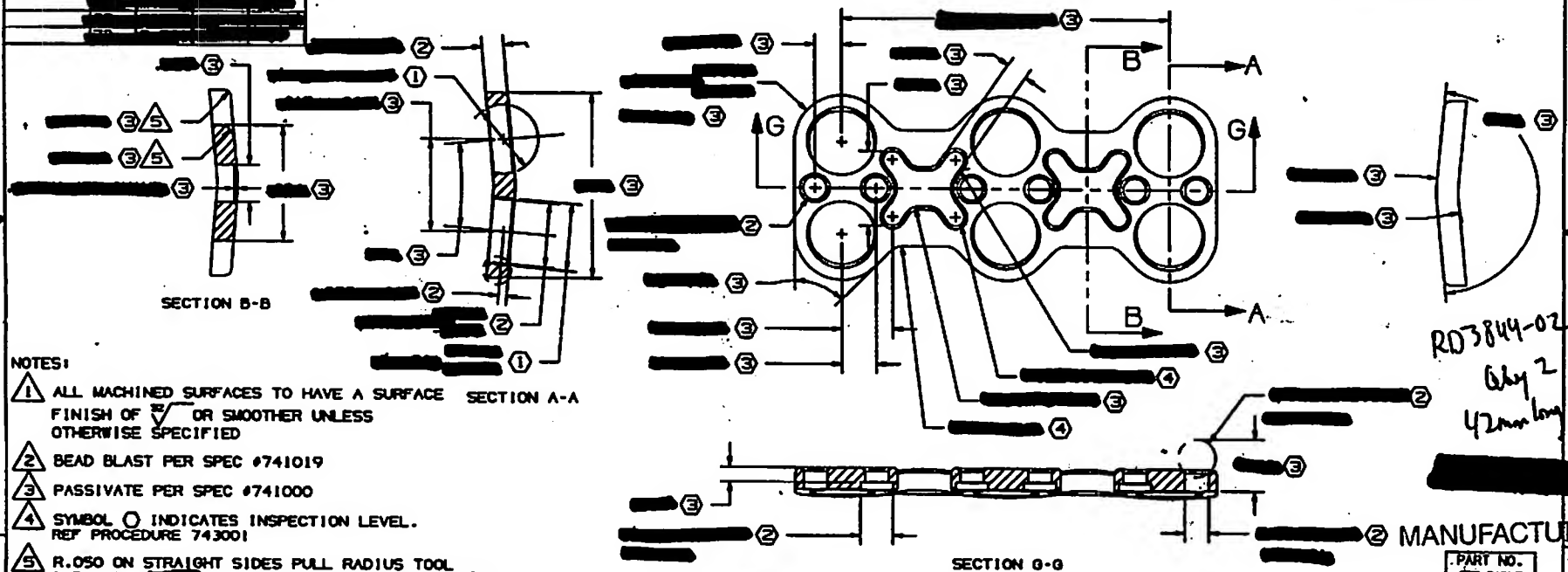


LASER ETCH DETAIL ON PLATE BOTTOM [redacted]



BENDING/FINISHING DETAIL [redacted]

HOLE DETAIL [redacted]
(REFERENCE FOR MACHINING/ PROGRAMMING ONLY)



NOTES:

1. ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF 32 OR SMOOTHER UNLESS OTHERWISE SPECIFIED
2. BEAD BLAST PER SPEC #741019
3. PASSIVATE PER SPEC #741000
4. SYMBOL ○ INDICATES INSPECTION LEVEL. REF PROCEDURE 743001
5. R.050 ON STRAIGHT SIDES PULL RADIUS TOOL OUT ALONG [redacted] TO A PARTIAL RADIUS OF [redacted] ALONG [redacted] ON THE ENDS OF THE PLATE
6. LONGITUDINAL BEND OF [redacted] AFTER MACHINING
7. SEE #741033 FOR HANDLING PRECAUTION
8. LASER ETCH PER SPEC #741005, IN AREAS SHOWN:
   - A) EBI
   - B) PART NUMBER
   - C) SIZE FROM TABLE
   - D) LOT NO., PER SPEC #741006

ISOMETRIC VIEW [redacted]

MANUFACTURING
PART NO. SEE TABLE

QTY	PART NUMBER	NOMENCLATURE OR DESCRIPTION	REMARKS	ITEM

LIST OF MATERIALS

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN INCHES
TOLERANCES:
2 PLACE DECIMALS ± .01
3 PLACE DECIMALS ± .005
FRACTIONS ± 1/64
ANGLES ± 1°

MATERIAL [redacted]
FINISH 1 2 3
HARDNESS
NEXT ASSY

DRAWN T. ZIOLO [redacted]
CHECKED
ENGINEERING APPR.
MANUFACTURING APPR.
QUALITY APPR.

TITLE
2-LEVEL PLATE
24MM - 70MM LENGTH

FIRST USED ON	SIZE	DWG NO.	REV.
[redacted]	C		A

SHEET 1 OF 1

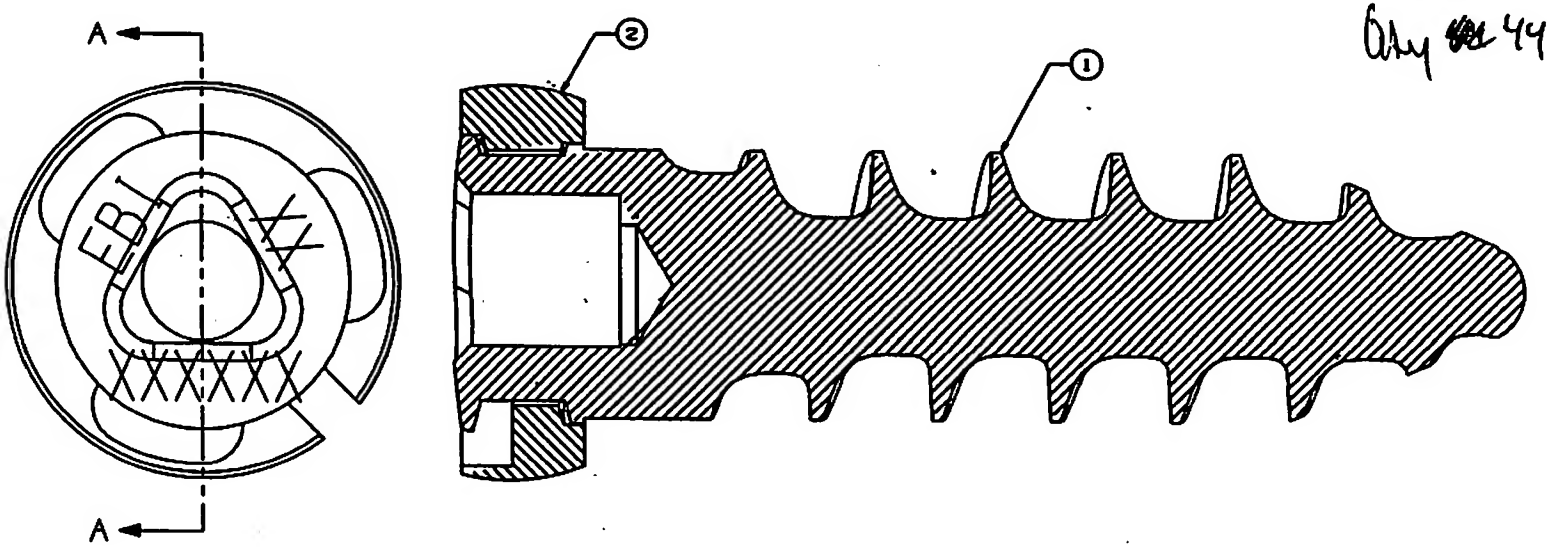
PART NO	LENGTH (MM)	ITEM 1	COLOR REF
	[redacted]		LIGHT GREEN
	[redacted]		GRAY
	[redacted]		DARK BLUE
	[redacted]		LIGHT BLUE
	[redacted]		DARK MAGENTA
	[redacted]		BRONZE

APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM

REVISIONS						
REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRFT	DATE	APPROVED
A		DCR-	RELEASED FOR DEVELOPMENT	TZ		

RD3844-03

Qty [redacted] 44



[redacted]

PART NO.
PART

MANUFACTURING

NOTES:

1. LASER ETCH PER SPEC #741005 PRIOR TO ASSEMBLY. IN AREAS SHOWN: CHARACTERS ARE TO BE [redacted] REF HIGH
   A) "EBI"
   B) LENGTH FROM TABLE
   C) LOT NO., PER SPEC #741006
2. SNAP ITEM 2 OVER ITEM 1. ROTATE TO RELAXED STATE.

ITEM	REMARKS	PART NUMBER	NOMENCLATURE OR DESCRIPTION	QTY
2		XXXXX	CERVICAL SPHERE FOR SCREW	1
1		SEE TABLE	SELF-TAPPING 4.0MM CERVICAL SCREW	1

LIST OF MATERIALS

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN INCHES
TOLERANCES:
2 PLACE DECIMALS ± .01
3 PLACE DECIMALS ± .005
FRACTIONS ± 1/64
ANGLES ± 1°
MATERIAL
FINISH
HARDNESS

DRAWN T. ZIOLO
APPROVED
[redacted]

TITLE CERVICAL 4.0MM SCREW ASSY

FIRST USED ON [redacted]
SIZE C
DWG NO. [redacted]
REV. A
SHEET 1 OF 1

NEXT ASSY

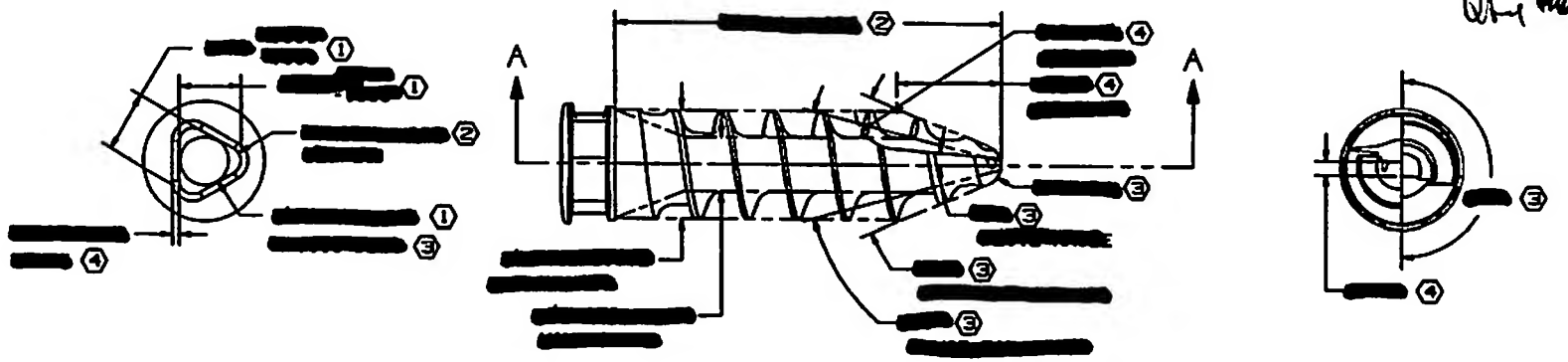
PART NO.	SIZE	LENGTH	DIM A	FINISH
[redacted]				TITANIUM ANODIZE AS PER EBI SPEC 060077.A00 COLOR (LIGHT GREEN)
[redacted]				PASSIVATE PER EBI SPEC #741000
[redacted]				TITANIUM ANODIZE AS PER EBI SPEC 060077.A00 COLOR (DARK BLUE)
[redacted]				TITANIUM ANODIZE AS PER EBI SPEC 060077.A00 COLOR (LIGHT BLUE)
[redacted]				TITANIUM ANODIZE AS PER EBI SPEC 060077.A00 COLOR (DARK MAGENTA)
[redacted]				TITANIUM ANODIZE AS PER EBI SPEC 060077.A00 COLOR (BRONZE)

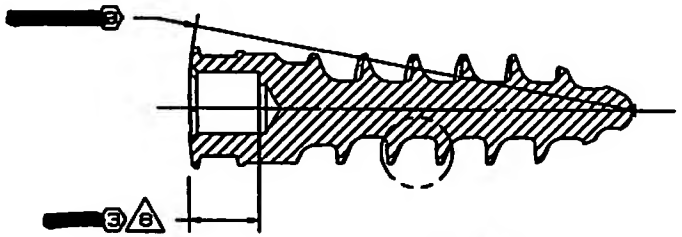
APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM

REVISIONS

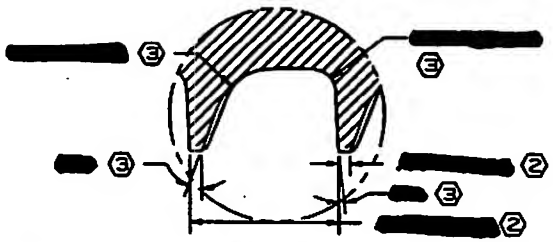
REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRFT	DATE	APPROVED
A		DCR-	RELEASED FOR DEVELOPMENT	TZ		

RD3844-04





SECTION A-A

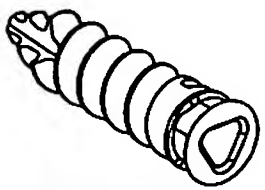


THREAD DETAIL

[redacted]

PART NO.
PART

MANUFACTURING



ISOMETRIC VIEW [redacted]

NOTES:

1. ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF 32 √ OR SMOOTHER UNLESS OTHERWISE SPECIFIED
2. BEAD BLAST PER SPEC #741019
3. SYMBOL ○ INDICATES INSPECTION LEVEL. REF PROCEDURE 743001
4. INSPECT PARTS USING OVERLAY NUMBER MXXXXX
5. SEE #741033 FOR HANDLING PRECAUTION
6. VISUAL END OF THREAD RUNOUT
7. REF DIMENSIONS FOR MACHINING AND PROGRAMMING ONLY
8. DIMENSION TO THEORETICAL CORNER
9. GEOMETRY SYM [redacted] ON CENTERLINE

QTY	PART NUMBER	NOMENCLATURE OR DESCRIPTION	REMARKS	ITEM

LIST OF MATERIALS

NEXT ASSY

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN INCHES
TOLERANCES:
2 PLACE DECIMALS ± .01
3 PLACE DECIMALS ± .005
FRACTIONS ± 1/64
ANGLES ± 1°

MATERIAL [redacted]

FINISH 1 2 SEE TABLE

HARDNESS

DRAWN T. ZIOLO [redacted]

APPROVED

RESPONSIBLE ENG.

QUALITY/RELIABILITY

MANUFACTURING ENG.

[redacted]

TITLE
SELF-TAPPING
4.0MM CERVICAL SCREW

FIRST USED ON
SPINAL SYSTEMS
CERVICAL PLATE
PROJ 0151

SIZE C

DWG NO. [redacted]

REV. A

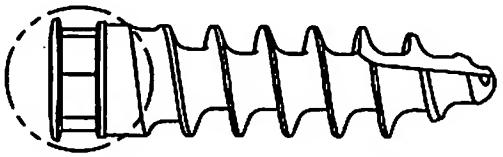
SHEET 1 OF 1

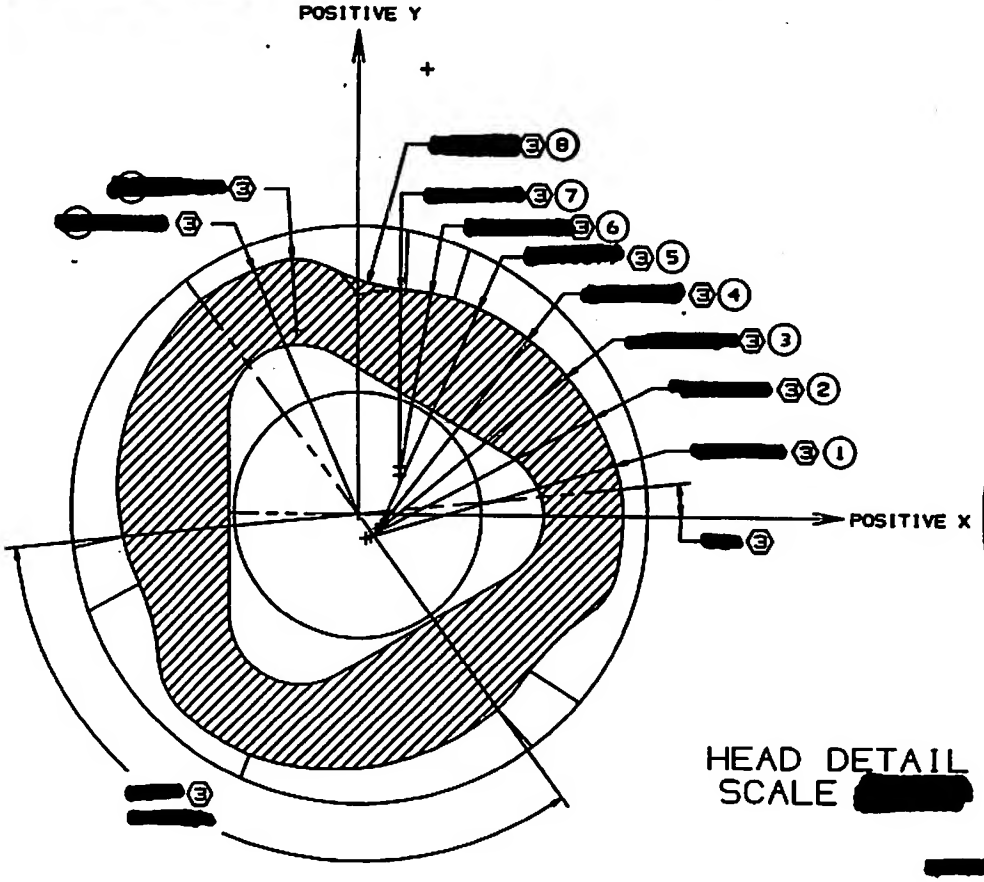
RADIUS NO.	RADIUS	X-CENTER	Y-CENTER
[redacted]			

REVISIONS
SEE SHEET ONE

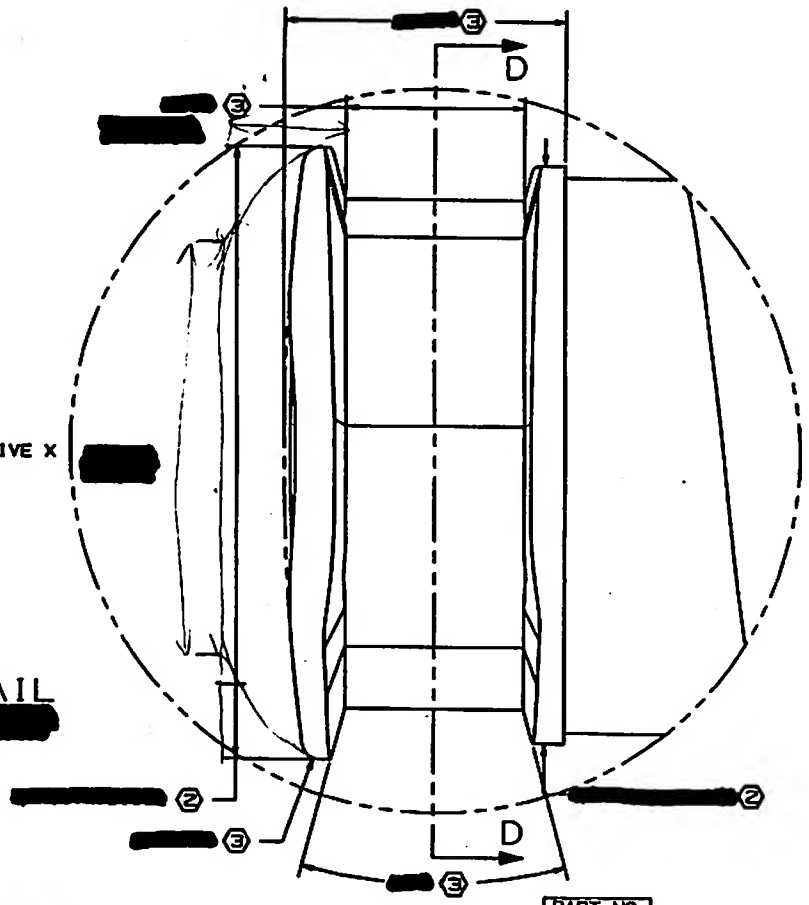
RD3844-04

Orig Rev 44





SECTION D-D



HEAD DETAIL
SCALE [redacted]

NOTES:

1. CAM PROFILE IS DIMENSIONED FOR ONE OF THE THREE LOBES. LOBES ARE [redacted] APART.
2. CAM ORIENTED WITH RESPECT TO THE TRIANGLE DRIVE AS SHOWN.

[redacted]

MANUFACTURING

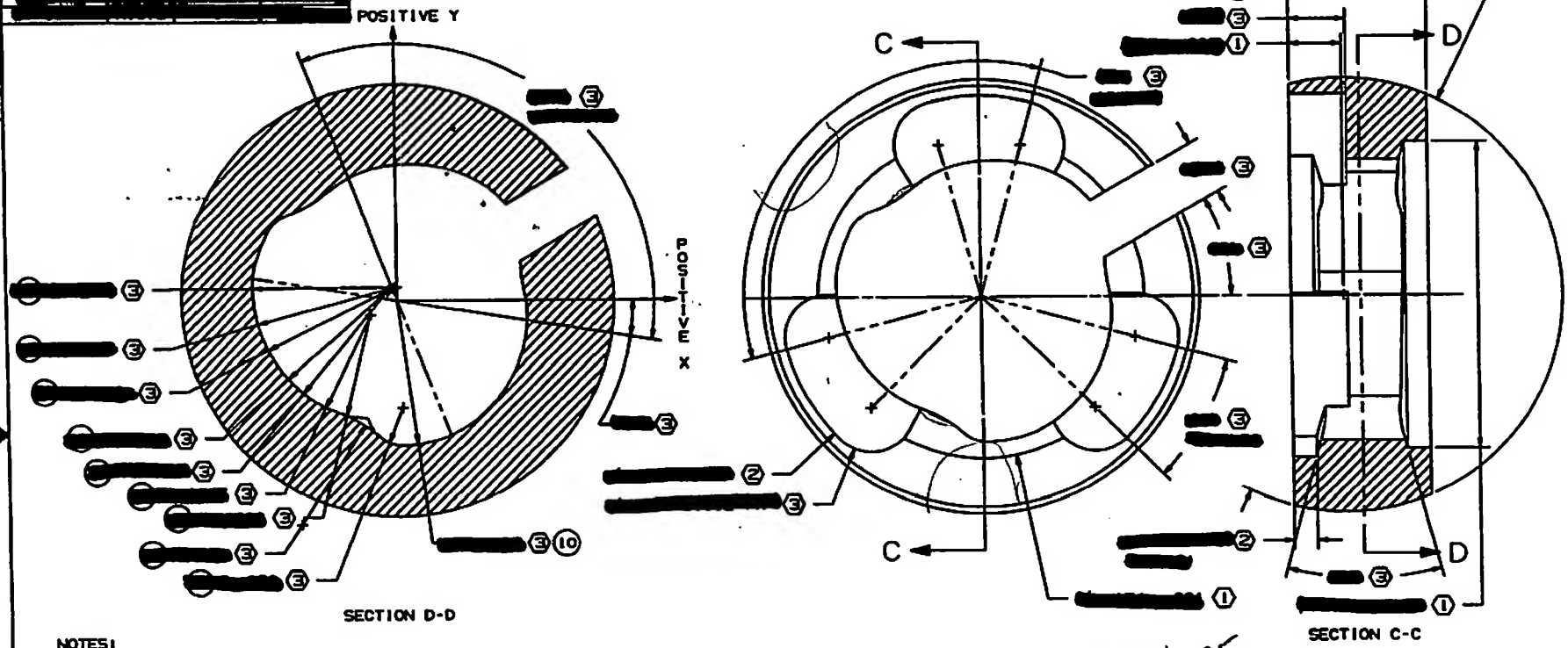
PART NO.
PART

[redacted]	SIZE C	DWG NO.	REV. A
	[redacted]	SHEET 2 OF 2	

APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM

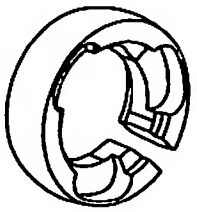
REVISIONS						
REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRFT	DATE	APPROVED
A		DCR-	RELEASED FOR DEVELOPMENT	TZ		

RAD	US NO.	RADIUS	X-CENTER	Y-CENTER
[redacted]				



NOTES:

1. ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF 32 OR SMOOTHER UNLESS OTHERWISE SPECIFIED
2. BEAD BLAST PER SPEC #741019
3. PASSIVATE PER SPEC #741000
4. TITANIUM ANODIZE AS PER EBI SPEC 060077.A00 COLOR (GOLD)
5. CAM PROFILE IS DIMENSIONED FOR ONE OF THE THREE LOBES. LOBES ARE [redacted] APART.
8. CAM ORIENTED WITH RESPECT TO THE DRIVE MECHANISM AS SHOWN.
7. THE NUMBER IN THE CIRCLE INDICATES WHICH RADIUS NUMBER TO REFER TO FOR THE CORRESPONDING X AND Y DIMENSIONS TO LOCATE ITS RESPECTIVE CENTER



ISOMETRIC VIEW [redacted]

RD3844-05

[redacted]

PART NO.
PART

MANUFACTURING

QTY	PART NUMBER	NOMENCLATURE OR DESCRIPTION	REMARKS	ITEM

LIST OF MATERIALS

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN INCHES
TOLERANCES:
2 PLACE DECIMALS ± .01
3 PLACE DECIMALS ± .005
FRACTIONS ± 1/64
ANGLES ± 1°

MATERIAL [redacted]
FINISH 1 2
HARDNESS

DRAWN T. ZIOLO
APPROVED
MANUFACTURING
QUALITY/RELIABILITY
ENGINEERING

TITLE CERVICAL SPHERE FOR SCREW

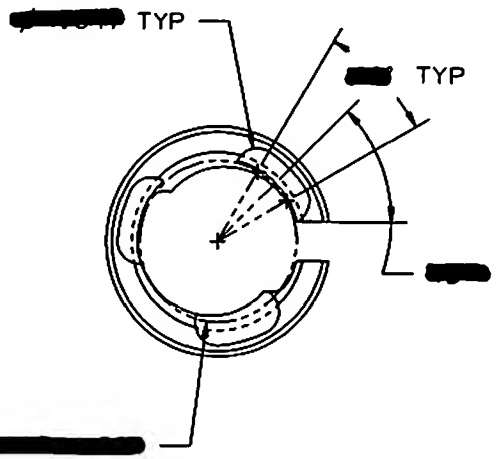
FIRST USED ON [redacted]
SIZE C
DWG NO. [redacted]
REV. A
SHEET 1 OF 1

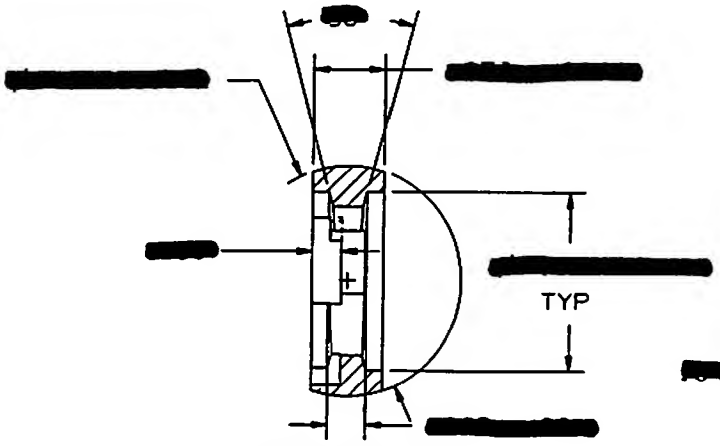
NEXT ASSY

APPROVALS MAINTAINED ELECTRONICALLY WITHIN AGILE SYSTEM

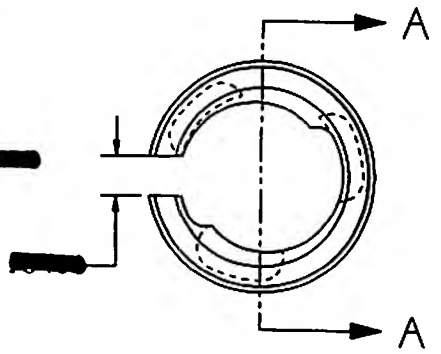
REVISIONS

REV	EN NO.	DCR/ECR No.	DESCRIPTION	DRFT	DATE	APPROVED
A			RELEASE FOR DEVELOPMENT	SW		





SECTION A-A



[redacted]

MANUFACTURING

PART NO.
RD3770-1

(3)

1. ALL MACHINED SURFACES TO HAVE A SURFACE FINISH OF $\sqrt{32}$ OR SMOOTHER UNLESS OTHEWISE SPECIFIED
2. MATERIAL TO MEET SPECS 065076.A00 AND ASTM F136.
3. PASSIVATE AS PER SPEC 741000

NEXT ASSY

QTY	PART NUMBER	NOMENCLATURE OR DESCRIPTION	REMARKS	ITEM

LIST OF MATERIALS

UNLESS OTHERWISE SPECIFIED
DIMENSIONS ARE IN INCHES
TOLERANCES:
2 PLACE DECIMALS ± .01
3 PLACE DECIMALS ± .005
FRACTIONS ± 1/64
ANGLES ± 1°

MATERIAL T16A14V (2)

FINISH (1)(3)

HARDNESS

DRAFTER [redacted]

APPROVED

RESPONSIBLE ENG. [redacted]

QUALITY/RELIABILITY

MANUFACTURING ENG.

[redacted]

TITLE DOUBLE CAM WASHER

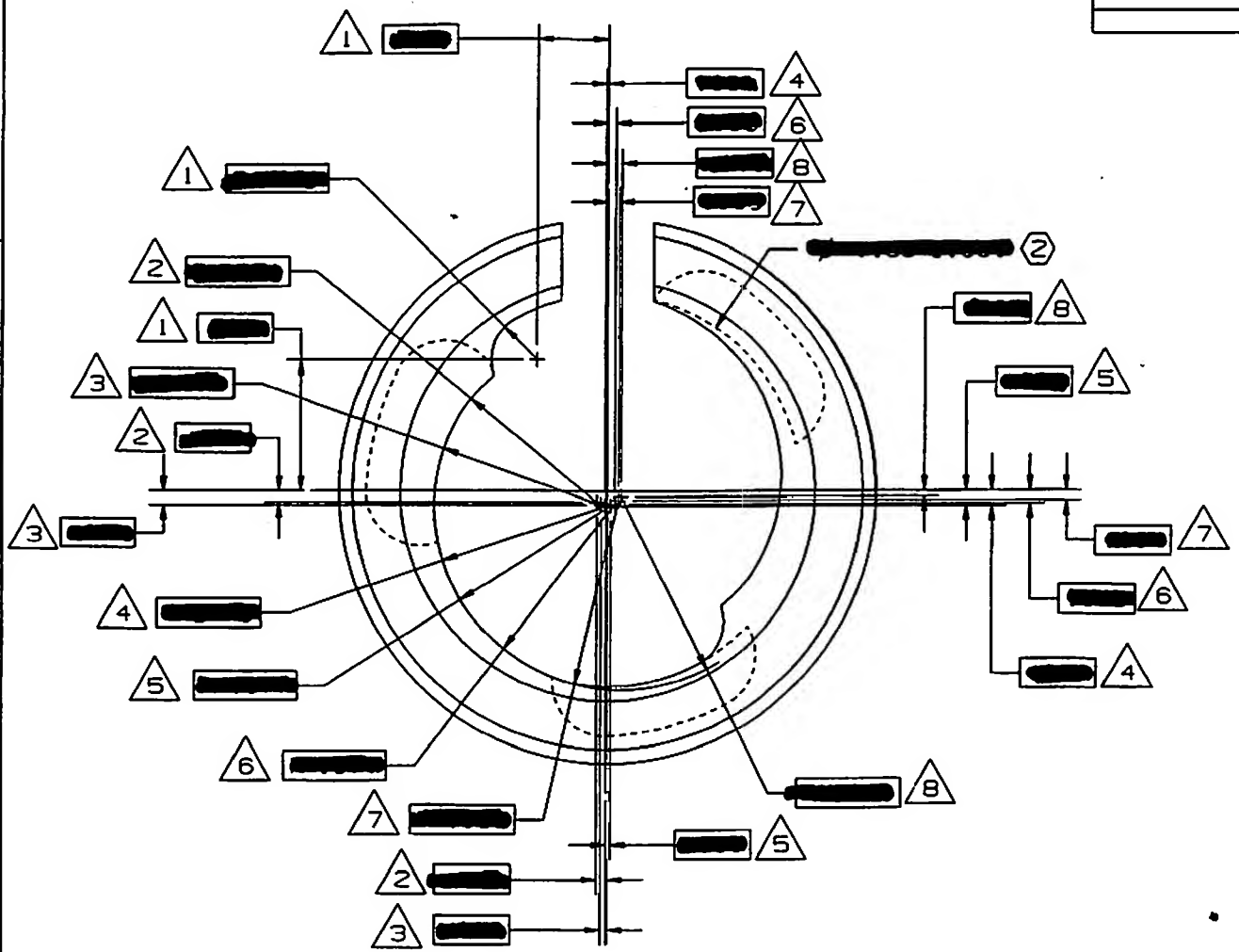
FIRST USED ON [redacted]

SIZE	DWG NO.	REV.
B	RD3770-1	A

SCALE [redacted] SHEET 1 OF 1

FILE No. [redacted] REV. 11/99

REVISIONS
SEE SHEET 1



[redacted]

MANUFACTURING

PART NO.
RD3770-1

[redacted]

NOTES:

1. NUMBERS IN TRIANGLES INDICATES WHICH RADIUS CORRESPONDS TO WHICH X AND Y DIMENSIONS
2. SYMBOL ⬡ INDICATES INSPECTION LEVEL REF PROCEDURE 743001

[redacted]

SIZE	DWG NO.	REV.
B	RD3770-1	A
[redacted]	SHEET 2 OF 2	

FILE No. [redacted] REV. 04/03